

## In the Specification

*Kindly replace paragraphs [0001] through [0003] with the following:*

### Related Application

This is a §371 of International Application No. PCT/FR2005/000338, with an international filing date of February 11, 2005 (WO 2005/077282 A1, published August 25, 2005), which is based on French Patent Application No. 04/01361, filed February 11, 2004.

### Technical Field

~~The present~~This invention refers to the field of spinal surgery.

### Background

In surgery of the spine, for example, for pedicular drilling, the bone cortex is often crossed, broken or damaged by the drilling instrument, that may then lead to ~~the~~ poor positioning of the pedicular screws. Following this poor positioning, the pedicular screws, inducing pain, paralysis, haemorrhage, etc. in the patient, may require another surgical intervention or, in certain cases, cause irreparable damage.

~~We are familiar with patent application FR2835732, filed by the present applicant, FR 2 835 732 discloses~~ a device to monitor ~~the~~ penetration of an instrument (~~dill~~drill or other type of instrument) in the vertebra by measuring the differences in the electrical impedance during ~~the~~ penetration~~[[,]]~~ so that the practitioner is constantly aware whether the end of the instrument is leaving the bone cortex and penetrating into a zone of soft tissue (marrow, nerves, tissue). In ~~this~~that case, the practitioner modifies the path of the penetration instrument ~~in order~~ to return to the bone cortex.

***Kindly replace paragraphs [0005] through [0041] with the following:***

To facilitate the repositioning of the penetration instrument during a drilling operation (or similar type of operation such as tapping, boring, etc.), but also to enable the proper positioning of the pedicular screw or any other surgical instrument, the practitioner has to know the exact position of the gaps formed during the drilling.

~~The present invention therefore aims at proposing~~It could therefore be advantageous to provide an exploration device indicating the position of the gaps formed during a drilling (or similar) operation.

#### Summary

This invention relates to an exploration device to monitor the penetration of an instrument in an anatomic structure including at least two electrodes, a source of voltage supplying the at least two electrodes, a means for measuring impedance between the electrodes, a means of angular location formed by at least one electrode punctually coinciding with a peripheral surface of the penetration instrument, the coinciding surface of the electrode having a position set off from a longitudinal axis of the instrument, and means for detecting a position of the at least one electrode.

#### Brief Description of the Drawings

Selected, representative aspects will be better understood using the following description that is only provided for explanatory purposes, with reference to the appended figures:

Fig. 1 is a diagram of an exploration device;

Fig. 2 is a front cutaway view of the distal end of the penetration instrument according to one configuration;

Fig. 3 is a longitudinal cutaway view of the penetration instrument according to another configuration;

Fig. 4 is a front cutaway view of the distal end of the penetration instrument according to still another configuration;

Fig. 5 is a perspective view of the penetration instrument according to yet another configuration; and

Fig. 6 is a longitudinal cutaway view of the penetration instrument according to a further configuration.

#### Detailed Description

~~For this purpose, the invention involves, according to its most general acceptance, an~~We disclose exploration devices to monitor ~~the~~ penetration of an instrument in an anatomic structure, in particular bone structure, comprising a source of voltage supplying at least two electrodes and a means to measure the impedance between the ~~aforementioned~~ electrodes, ~~and is it remarkable in that the aforementioned.~~ The device includes a means of angular location formed by at least one electrode punctually coinciding with a peripheral surface of the ~~aforementioned~~ penetration instrument, the coinciding surface of the ~~aforementioned~~ electrode (3) whose position is set off from the longitudinal axis of the ~~aforementioned~~ instrument, as well as a means to detect the position of the ~~aforementioned~~ electrode (3).

By “punctual coincidence” and “punctually coinciding,” we mean a contact surface partially and discontinually coinciding with the peripheral surface of the aforementioned penetration instrument. In particular, an angular contact surface, and by extension a tubular shape are not considered as providing punctual coincidence.

Depending on whether one desires taking lateral readings or readings at the end of the penetration instrument or laterally and at the end, respectively, the penetration instrument ~~will~~may be equipped with at least one electrode coinciding with the lateral surface of the ~~aforementioned~~

penetration instrument and/or at least one electrode coinciding with the peripheral surface of the distal end of the ~~aforementioned~~ penetration instrument.

Advantageously, the ~~aforementioned~~ coinciding electrode is driven in rotation, the ~~aforementioned~~ coinciding electrode being driven at speed of rotation so that it sweeps at least 360 degrees per level of insertion of the ~~aforementioned~~ penetration instrument in the bone structure.

~~Preferably, the aforementioned~~ The device may comprise[[s]] a plurality of angularly spaced coinciding fixed electrodes and ~~that~~ the means to measure the impedance delivers a signal corresponding to each of the ~~aforementioned~~ electrodes.

~~Advantageously, the aforementioned~~ The electrodes may consist of punctual contacts longitudinally and angularly spaced out.

~~Advantageously, the aforementioned~~ The electrodes ~~are~~ may be formed by longitudinal strips.

According to one ~~specific~~ selected configuration ~~of the invention~~, the electrodes are distributed around the longitudinal axis of the penetration instrument.

~~Advantageously, the~~ The electrodes ~~are~~ may be symmetrically arranged with respect to the longitudinal axis of the ~~aforementioned~~ penetration instrument.

~~Advantageously, the aforementioned~~ The electrodes may consist of conducting rods of circular, semi-annular, rectangular and/or triangular section. In addition, they may consist of eccentric conducting rods.

According to the realm of intervention in which the penetration instrument is used, the ~~aforementioned~~ device may comprise at least one electrode at its distal end(s). ~~Advantageously, the aforementioned~~ The device may also comprise[[s]] two electrodes arranged at the distal end of the ~~aforementioned~~ penetration instrument, the ~~aforementioned~~ electrodes consisting of conducting rods of concentric circular section.

~~Advantageously, the aforementioned~~The means of detection may consist[[s]] of visual marking preferably on the handle of the ~~aforementioned~~ exploration device. According to one specific means of creation of the device, the ~~aforementioned~~ handle (6) forms the ~~aforementioned~~ means of detection.

~~Advantageously, the aforementioned~~The device may also comprise[[s]] a central channel for the passage of an additional instrument.

~~Now, the invention will better be understood using the following description that is only provided for explanatory purposes, with reference to the appended figures:~~

~~—— figure 1 illustrates a diagram of an exploration device according to the invention;~~

~~—— figure 2 illustrates a front cutaway view of the distal end of the penetration instrument according to a first configuration of the invention;~~

~~—— figure 3 illustrates a longitudinal cutaway view of the penetration instrument according to a second configuration of the invention;~~

~~—— figure 4 illustrates a front cutaway view of the distal end of the penetration instrument according to a third configuration of the invention;~~

~~—— figure 5 illustrates a perspective view of the penetration instrument according to a fourth configuration of the invention; and~~

~~—— figure 6 illustrates a longitudinal cutaway view of the penetration instrument according to a fifth configuration of the invention.~~

~~According to the invention~~Turning now to the Drawings, the exploration device (1), illustrated in ~~figure~~Fig. 1, is a device enabling the monitoring of the penetration of an instrument (2) in the bone structures of a human or animal body, the ~~aforementioned~~ structures ~~presenting~~having at least two different zones of electrical impedance.

The exploration device (1) comprises a source of voltage (~~not represented~~shown) supplying at least two electrodes and a means to measure the impedance (~~not represented~~) between the ~~aforementioned~~ electrodes.

At least one of the ~~aforementioned~~ electrodes is found on the ~~aforementioned~~ penetration instrument (2).

The ~~aforementioned~~ device also comprises means ~~offor~~ signalling producing a signal at the time of detection, by impedometer, a variation of impedance, and therefore the presence of a gap. The ~~aforementioned~~ means ~~offor~~ signalling ~~consist of the~~includes emission of a visual signal, such as a light, a sound signal, and/or a tactile signal (vibrator, etc.).

~~According to one advantageous mode of creation of the invention, the aforementioned~~The device may also comprise[[s]] means for the acquisition and visualisation of the position of the gaps during ~~the~~ penetration of the instrument (2) in the bone structure.

According to the applications considered, the penetration instrument (2) may either be fixed, or manually driven in rotation by means of drive of the motor type (~~not represented~~shown).

Therefore, it may ~~consist,~~include in the ~~first~~one configuration, for example, of a probe, a square tip, a spatula, a curette or other, and in ~~the~~a second configuration, for example, of a screw, a drill, a tap, or other.

In the following section, the penetration instrument (2) ~~consists of~~includes a probe (2). However, the configurations presented are of course applicable to ~~the~~ other penetration instruments mentioned above.

Figure. 2 illustrates ~~the first~~one configuration of the probe (2) forming the ~~aforementioned~~ exploration device (1).

In this ~~first~~ configuration, the penetration instrument (2) ~~presents~~has two eccentric electrodes (3, 4) of circular section at its distal end, electrode (3) being surrounded but separated from electrode (4) by an insulation ring (5).

In this example, electrode (3) comprises the positive pole of the ~~aforementioned~~ electronic device, the negative pole of the ~~aforementioned~~ electronic device ~~consisting of~~comprising the electrode (4). ~~It is obvious that this~~This is only one example of a creation and that the man of the art ~~may create an electronic device whose positive pole consists of~~includes the electrode (4) and the negative pole of the electrode (3) ~~without going beyond the invention~~. Variations are within the skill in the art.

Each electrode (3, 4) is arranged ~~so as to~~ coincide with the surface of the ~~aforementioned~~ penetration instrument (2).

To avoid any disturbance of the signal, the surface of the central or internal electrode (3) coinciding with the surface of the ~~aforementioned~~ penetration instrument (2) remains relatively small with respect to the dimensions of the hole made in the bone cortex during the drilling (or other) operation.

The position of the electrode (3) is detected by specific marking on the ~~aforementioned~~ exploration device (1). Advantageously, the marking is carried out by means of the handle (6) of the ~~aforementioned~~ exploration device (1). It may, for example, ~~consist of~~include a visual signal, for example, an arrow, represented on the handle (6). The marking may also ~~consist of~~include any means directly on the handle (6), such as, for example, a specific shape of the ~~aforementioned~~ handle (6).

Therefore, during ~~the~~ penetration of the instrument (2) in the perforated bone structure, a signal is given off by the ~~aforementioned~~ means ~~off~~or signalling when a variation in impedance

measured between the electrodes (3, 4) is detected by the impedometer, indicating the presence of a gap.

Following ~~this~~such detection, the means ~~offor~~ signalling emit a warning signal (visual, sound or tactile). The practitioner then knows that the electrode (3) from the penetration instrument is positioned in front of a gap.

The practitioner then determines the direction of the gap with the mark corresponding to the position of the electrode (3) marked on the handle (6) of the ~~aforementioned~~ exploration device (1).

In order to enable full scanning of the bone structure, the ~~aforementioned~~ penetration instrument (2) is endowed with a movement of rotation, the speed of rotation exceeding the speed of progress of the penetration instrument (2) in the bone structure. In other ~~terms~~words, the speed of rotation of the ~~aforementioned~~ instrument (2) is such that the aforementioned penetration instrument (2) sweeps at least 360 degrees by level of penetration.

~~Figure.~~ 3 illustrates a ~~second~~another configuration of the probe (2) comprising the ~~aforementioned~~ exploration device (1), which enables ~~the~~ detection of gaps laterally arranged with respect to the body of the ~~aforementioned~~ penetration instrument (2).

In this ~~second~~ configuration, the electrode (3) is positioned in the ~~aforementioned~~ penetration instrument (2) ~~so as to~~ punctually coincide with the lateral surface of the ~~aforementioned~~ penetration instrument (2).

As for the electrode (4), it is distributed on the rest of the lateral surface of the ~~aforementioned~~ penetration instrument (2), including its distal end. The ~~aforementioned~~ electrodes (3, 4) ~~are~~ separated from each other by an insulant (5).



***Kindly replace paragraphs [0043] through [0044] with the following:***

Figure 4 illustrates a ~~third~~another configuration of the probe (2) comprising the ~~aforementioned~~ exploration device (1), which enables detection of gaps arranged at the end of the ~~aforementioned~~ penetration instrument (2).

In this ~~third~~ configuration, the penetration instrument (2) ~~presents~~has three electrodes (7, 8, 9) of sensibly identical triangular section at the distal end. The ~~aforementioned~~ electrodes (7, 8, 9) distributed around the longitudinal axis of the penetration instrument (2) are angularly spaced. Advantageously, the angular space is identical.

***Kindly replace paragraphs [0046] through [0051] with the following:***

Since the number and triangular shape of the electrodes is given here by way of example, it is understood that the ~~aforementioned~~ penetration instrument (2) may ~~present~~have a greater number of electrodes and a shape other than triangular. The determination of the direction of the gaps is all the more exact when the number of electrodes distributed at the end of the ~~aforementioned~~ instrument (2) is higher.

Figure 5 illustrates another configuration of the probe (2), enabling detection of the gaps arranged at the end of the ~~aforementioned~~ penetration instrument (2), but also laterally.

In this configuration, the ~~aforementioned~~ penetration instrument (2) ~~consists of~~includes a plurality of electrodes coinciding with the lateral surface of the ~~aforementioned~~ penetration instrument (2) and at the distal end of the ~~aforementioned~~ penetration instrument (2).

Since the position of each electrode is known, it is then possible, ~~as in the third configuration,~~ to determine the position of the gap by the emission of a signal by the impedometer corresponding to the electrode positioned in front of the gap.

In the configurations presented above, the means to determine the position of the gaps ~~consist of~~include fixed electrodes. According to ~~a specific yet another~~ configuration of the ~~aforementioned~~ penetration instrument (2) (not ~~represented~~shown), the gaps may also be determined by means of one or several mobile electrodes.

In addition, in the previous examples, the electrodes (3, 4) are respectively carried by the ~~aforementioned~~ penetration instrument (2). Of course, the ~~aforementioned~~ penetration instrument (2) may be equipped with only one electrode (3), the other electrode being positioned on the patient, and more specifically, on a surface other than the surgical wound, without going beyond the field of the invention.

***Kindly replace paragraphs [0053] through [0054] with the following:***

In particular, in the case where the penetration instrument (2) ~~consists of~~includes a drill element, the ~~aforementioned~~ penetration instrument (2) may advantageously comprise at least one electrode (13) coinciding with the lateral surface of the ~~aforementioned~~ penetration instrument (2), as well as two electrodes (10, 11) concentrically arranged at the distal end of the ~~aforementioned~~ penetration instrument (2) (~~figure~~Fig. 6). It is therefore possible, due to the configuration of the ~~aforementioned~~ penetration instrument (2) to determine the presence and direction of a gap by means of electrodes (11 and 13), as well as prevent any possible perforation of the bone cortex using electrodes (10 and 11). For this purpose, the positioning of a lateral electrode consisting of a rod extending to the distal end should be avoided. If fact, it would likely be impossible~~[[,]]~~ with such a configuration~~[[,]]~~ to know whether the zone detected by the electrodes is lateral or distal.

~~The invention~~This disclosure is described above by way of example. It is understood that ~~the~~ man of one skilled in the art is able to create different ~~variants~~variations of the ~~invention~~structures

described and/or shown without ~~going outside of the patent~~ departing from the subject matter recited  
in the appended claims.